

Remarks

Claims 31-36, 38-43, and 50-63 are pending in the subject application. By this Amendment, Applicant has canceled claims 51 and 52, amended claim 32, and added new claims 108 and 109. Accordingly, claims 31-36, 38-43, 50, 53-63, 108, and 109 are currently before the Examiner. Favorable consideration of the pending claims is respectfully requested.

Claims 31-36, 38-43, and 50-63 are rejected under 35 USC §112, first paragraph, as non-enabling. The Examiner asserts that the specification, while being enabling for a vaccine composition that induces a protective immune response against two or more subtypes of FIV, comprising an effective amount of an FIV immunogen that minimally includes the FIV envelope glycoprotein, does not enable those vaccine embodiments that do not encompass envelope glycoprotein from at least two different FIV subtypes. Applicant notes that claim 32 has been amended to recite that the immunogen comprises an FIV envelope protein. Applicant respectfully traverses this rejection.

Applicant respectfully asserts that the pending claims are enabled. As noted above, the Examiner asserts that the claims are only enabled for immunogens comprising FIV envelope protein. However, Applicant respectfully submits that the Examiner has not provided any basis to support the assertion that the subject specification is not enabled for compositions comprising immunogens other than FIV envelope protein. Under the authority of *In re Marzocchi*, 169 USPQ 367 (CCPA 1971), Applicant's statements must be taken as true unless the Patent Office can recite specific reasons to doubt the validity of those statements. Moreover, there is no requirement that an applicant for patent test each and every possible embodiment encompassed within the scope of the claims in order to satisfy the requirements of 35 USC §112, first paragraph. *In re Angstadt*, 190 USPQ 214 (CCPA 1976). Applicant submits that immunogens other than FIV envelope proteins can be utilized with the claimed invention. For example, the subject specification teaches and exemplifies the use of cells infected with FIV (see page 5, lines 6-7, and Example 2 of the subject specification).

In addition, submitted herewith are publications that show that FIV proteins other than envelope protein, such as a protein encoded by FIV *gag* gene, can induce an immunogenic response. Submitted herewith are U.S. Patent Nos. 5,820,869; 5,989,562; and 5,833,993; EPO Patent No. EP 956360; and a publication by Coleman *et al.* (2005) that show the use of FIV proteins other than

envelope proteins in the context of single subtype immunogens. The ‘869 and ‘562 patents show use of *gag* gene products to prevent and treat FIV infection (see, for example, claims 1, 3, 8, and 12 of the ‘562 patent, and column 14, lines 16-23, of the ‘869 patent). The ‘993 patent shows that a combination of *env* and *gag* gene products provided protection against FIV infection (see, for example, “Example 2” at column 13, line 46 through to column 14, line 58, and particularly the “Results” at lines 50-58). The EPO ‘360 patent shows that *gag* and *pro* gene products provided protection from infection by FIV (see, for example, Table 3 of the EPO ‘360 patent). The Coleman *et al.* publication shows the use of FIV p24 as an immunogen to provide protection against FIV infection (see, for example, page 1458-1460, including Tables 1 and 2, study groups 2-2 and 2-3). These patents and publications demonstrate that immunogens comprising gene products other than FIV envelope protein, such as *gag* and *pol* gene products, can function as immunogens to induce a protective immune response against infection by FIV.

In addition, Applicant respectfully asserts that the present invention claims a composition that comprises an “effective amount” of FIV immunogen from or comprising at least two different FIV subtypes. Applicant is not claiming those amounts and conditions of immunogens that do not provide protection against infection by two or more subtypes of FIV. In view of the remarks herein, reconsideration and withdrawal of the rejection under 35 USC §112, first paragraph, is respectfully requested.

It should be understood that the amendments presented herein have been made solely to expedite prosecution of the subject application to completion and should not be construed as an indication of Applicant’s agreement with or acquiescence in the Examiner’s position.

In view of the foregoing remarks and amendments to the claims, Applicant believes that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

Applicant invites the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



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Attachments: copy of U.S. Patent No. 5,820,869
copy of U.S. Patent No. 5,989,562
copy of U.S. Patent No. 5,833,993
copy of EPO Patent No. EP 956360
copy of the Coleman *et al.* (2005) publication.